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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,463	05/26/2000	Carl J. Wheeler	VCAL100-1	2067

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W., SUITE 600  
WASHINGTON, DC 20005-3934

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/580,463

Applicant(s)

Wheeler

Examiner

Richard Schnizer

Art Unit

1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 20, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 47-94 is/are pending in the application.
- 4a) Of the above, claim(s) 50-67, 71-73, and 87-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-49, 79-81, and 83 is/are rejected.
- 7) ☒ Claim(s) 68-70, 74-78, 82, 84-86, 93, and 94 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 26, 2000 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16 6) ☐ Other:

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### DETAILED ACTION

An amendment was received and entered as Paper No. 15 on 10/25/02.

Copies of IDS's originally submitted as Paper Nos. 2 and 3 were received and on 6/26/02 and entered into the file as Paper No. 16 on 10/30/02.

Claims 47-94 are pending in the Application.

Previously Applicant elected without traverse of group I, claims 47-94, drawn to compositions comprising a cationic lipid, and methods of delivering a biologically active agent to an animal cell is acknowledged, and the species of  $R_9$  wherein  $R_9$  comprises  $NR_{12}-C(O)-NR_{13}-R_{16}-NR_{14}-C(O)-NR_{15}$ . Claims 47, 48, 68-70, 74-86, 93, and 94 read on this species. A search of the prior art indicated that this species was novel and non-obvious. In accordance with MPEP 603.02, the search was extended to include  $C_1-C_{10}$  substituted alkyl groups. See rejections under 35 USC 102, below. This species reads on claims 47-49 and 76-86. Claims 47-49, 68-70, 74-86, 93, and 94, and the species of  $R_9 = NR_{12}-C(O)-NR_{13}-R_{16}-NR_{14}-C(O)-NR_{15}$  and  $R_9 = C_1-C_{10}$  substituted alkyl groups are under consideration in this Office Action.

This is a non-final Office Action due to the failure to clearly point to the appropriate structure in the Spadini reference (see 102 and 103 rejections below), and because of a new ground of rejection under 112, second paragraph.

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***Rejections and Objections Withdrawn***

1. Applicant's amendment overcomes the objection to claim 82 and dependents which formerly recited non-elected subject matter.

The rejection under 35 USC 112, first paragraph of claims 47-49, 68-70, 74-76 for new matter is withdrawn in view of Applicant's persuasive argument.

After further consideration the rejection under 35 USC 112, second paragraph of claims 47-49, 68-70, 74-86, 93, and 94 as indefinite over the term "non-toxic anion" is withdrawn.

***Claim Objections***

2. Claims 68-70, 74-78, 82, 84-86, 93, and 94 are objected to as depending from a rejected claim but would be allowable if rewritten in independent form incorporating all the limitations of the parent claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 79-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 79-81 recite "the encoded antigen" without antecedent basis. Claim 79 should be amended to depend from claim 77.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 47-49 stand rejected under 35 U.S.C. 102(b) as being anticipated by Spadini et al (US Patent 3,983,079).

Spadini teaches a composition according to the structure recited in instant claims 47 and 48, wherein R9 is the substituted alkyl group CH<sub>2</sub>-CHOH-CH<sub>2</sub>. See e.g. column 3, lines 60-65 and column 13, lines 28-30 which discloses tetramethyl-di-(octoxy-beta-hydroxypropyl)-beta-hydroxypropylene-diammonium chloride. Also see enclosed search result.

Thus Spadini anticipates the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 83 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Spadini et al (US Patent 3,983,079).

Spadini teaches a composition according to the structure recited in instant claim 83, wherein R9 is the substituted alkyl group  $\text{CH}_2\text{-CHOH-CH}_2$ . See e.g. column 3, lines 60-65 and column 13, lines 28-30 which discloses tetramethyl-di-(octoxy-beta-hydroxypropyl)-beta-hydroxypropylene-diammonium chloride. Also see enclosed search result.

Spadini fails to teach a kit or a container comprising the composition, but it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the composition of Spadini into a container in order to store it, such procedures being routine in the art. It is noted that although Spadini fails to teach a polynucleotide and means for administering the composition to a vertebrate, these limitations are optional and need not be taught.

Thus the invention as a whole was *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 10/25/02 have been fully considered but they are not persuasive.

Applicant argues that Spadini does not teach the claimed lipid because Spadini fails to allow for a hydroxy, ether, or ester substituent at the R1-Z1 or R2-Z2 positions of the instantly

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claimed structure. This is unpersuasive because Spadinin teaches tetramethyl-di-(octoxy-beta-hydroxypropyl)-beta-hydroxypropylene-diammonium chloride, which comprises an oxygen at Z1 and Z2, and octane group at R1 and R2. See column 13, lines 28-30, and the enclosed search result.

For these reasons the rejections are maintained.

*Summary*

Claims 47-49, 68-70, 74-86, 93, and 94 are under consideration.

Claims 79-81 are indefinite.

Claims 47-49 are anticipated.

Claim 83 is obvious.

Claims 68-70, 74-78, 82, 84-86, 93, and 94 are objected to as depending from a rejected claim but would be allowable if rewritten in independent form incorporating all the limitations of the parent claims.

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*Conclusion*


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

  
JEFFREY SIEW  
PRIMARY EXAMINER  
1/11/03